

### **REMARKS**

Claims 1 to 11, 14 to 22 and 24 to 32 are currently pending in the application. All of the pending claims have been rejected.. By this amendment, Applicants have amended claims 1, 11, 20 and 32. No new matter has been added by the amendments, all of the amendments having full support in the specification and drawings as filed. In view of the above amendments and the following remarks, Applicants respectfully submit that this application is in condition for allowance. Accordingly, reconsideration and a timely notice of allowance are respectfully requested.

#### **Claim Amendments**

Claims 1 and 11 have been amended to recite that the female connector comprises “a longitudinal axis and a face having a plurality of castellations spaced about the longitudinal axis.” Full support for these amendments is found in the specification and drawings as filed, for example in Figs. 3, 5, 6 and 7 as well as par. 84 of the published application.. Claims 20 and 32 have been amended for clarity to recite that the grip is slidable on a shaft. Full support for these amendments is found in the specification and drawings as filed, for example in Fig. 1 and par. 63 of the published application. Finally, claim 32 was amended to correct a typographical error.

No new matter has been added by the amendments, full support for the amendments being found in the specification and drawings as filed. Entry of the amendments to the claims is respectfully requested.

#### **Rejections Under 35 U.S.C. §112, Second Paragraph**

Claim 24 is rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the Examiner states that claim 24 recites the limitation “the syringe” in line 2 without proper antecedent basis. Applicants respectfully traverse this rejection and submit that proper antecedent basis for “the syringe” in line 2 is found in line 1 which recites “A syringe adapted for connection to the second converter of a kit as claimed in claim 11.”

Accordingly, Applicants respectfully request that this rejection be withdrawn.

### **Rejections Under 35 U.S.C. §102**

Claims 1, 2, 7 to 16, 18 to 27, 29, 31 and 32 are rejected under 35 U.S.C. §102(b) as being anticipated by Segal et al. (U.S. Patent No. 6,402,207). Claims 12, 13 and 23 have been canceled without prejudice, but Applicants respectfully traverse this rejection as to the remaining claims.

Claim 1, as amended, recites a female component having “a longitudinal axis and a face having a plurality of castellations spaced the longitudinal axis” where “leak paths are provided between said castellations.” Claim 11, as amended, recites a different female connector that “comprises a longitudinal axis and a face having a plurality of castellations spaced about the longitudinal axis, whereby leak paths are provided between said castellations.” Applicants respectfully submit that Segal et al. fail to teach or suggest these limitations.

The present invention is directed to a system for preventing misconnections between different applications of medical tubing. Typically, medical tubing of all applications is connected using male and female luer fittings. The present invention has a connector system with male and female connectors that may utilize luer similar cones and sockets. The male and female connectors form a key that prevents interchangeability between different applications.

The female connectors have a longitudinal axis and a face having a plurality of castellations spaced about the longitudinal axis. Leak paths between the castellations prevent anyone from inserting a standard male luer fitting into the female component. As explained in the specification, on par. 84 of the published application, the castellations provide a substantial obstacle to inadvertent and even malicious misconnection between tubing of different applications.

While Segal et al. state generally that misconnections will cause leakage, there is no teaching or suggestion of specific structure to prevent a male luer fitting from being used in connection with the fittings taught by Segal et al. See Segal, col. 6, line 65 to col. 7, line 10. The portion of Segal et al. cited by the Examiner for teaching castellations (col. 6, lines 33 to 37)

recites:

“According to one practice, the illustrated connector 86 couples to the other connector half to complete the medical connection. According to one practice, the illustrated connector 86, when not coupled to its mating connector, generally cannot be connected to any standard syringe or medical tubing which is devoid of a complementary surface feature.”

The portion cited by the Examiner does not discuss castellations spaced about a longitudinal axis. Moreover, a review of connector 86 in Fig. 4, reveals no castellations. Applicants further submit that one skilled in the art would have no motivation to modify the structure of Segal et al. to have the specific structure of castellations spaced about a longitudinal axis with leak paths in between.. Accordingly, Applicants submit that claims 1 and 11 are patentable over Segal et al. on this basis.

Additionally, claim 1 recites that “said grip has application affordance unique to the application for which it is intended, the affordance comprising both visual and tactile cues.” Applicants continue to respectfully submit that Segal et al. fail to teach or suggest this limitation. Applicants hereby incorporate by reference the remarks previously submitted in the Amendment and Response to Office Action filed on September 6, 2007.

Additionally, claim 11, as amended, recites standard male and female connectors each having standard connectors and different connectors. The “standard connectors are 6% luer connectors” and the “different connectors are reduced diameter 6% conical connectors”. Conical connectors, which are familiar to the medical industry, are easy and convenient to use and are well-tried and tested.

The Examiner cites to col. 6, lines 33 to 37 of Segal et al. for teaching the 6% luer connectors. However, as seen from the quote above, the portion cited by the Examiner does not specifically recite 6% luer connectors.

Claims 7 to 10, 14 to 16, 18 to 27, 29, 31 and 32 depend from claims 1 and 11 and by definition contain all of the limitations of claims 1 and 11 respectively. Accordingly, Applicants respectfully submits that claims 2 to 10, 14 to 16, 18 to 27, 29 and 31 are patentable over Segal et al. for the reasons given above for claims 1 and 11 as well as because of the additional

limitations contained therein.

For example, claim 2 further recites “wherein said application affordance comprises a shape of the grip that is suggestive of a part of a human body for which the application is intended.” The Examiner states that Segal et al. teach this limitation in col. 8, lines 33 to 49 and col. 2, lines 12 to 19 and col. 5, lines 31 to 46 and Figs. 1 and 7A. The portions of the specification cited by the Examiner are reproduced below for convenience:

Col. 8, lines 33 to 49:

The foregoing safety medical connectors are designed to be interposed between existing devices for medical infusions, injections, or aspirations. An additional feature of the present invention is the fusion of a half connector as illustrated in FIG. 1 into a standard medical connector or device. FIGS. 7A through 7D illustrate the incorporation of a safety connector half into an epidural catheter connector 500, which in turn is connected to an epidural catheter 505. Any of the mating and locking configurations of the present invention, for example the rectangular surface feature 510, can be incorporated into the end of the epidural catheter connector. The epidural catheter connector in turn mates with a complementary safety connector half 520. This connector half includes a complementary shaped surface feature that ensures that only medications intended for epidural delivery are injected through the epidural catheter, since only a specific surface feature 510 can mate with the connector half 520.

Col. 2, lines 12-19:

The present invention addresses this problem by replacing the universal connector with unique specially configured male/female connector pairs, each coded for use with only one type of medical catheter or device (e.g., peripheral intravenous catheter, central venous catheter, arterial catheter, epidural catheter, dialysis catheter).

Col. 5, lines 31 to 46:

The illustrated medical connector portions 1, 3 of the invention are designed to be application or path-specific. The male or first connector portion 1 of the medical connector 40 is configured to mate with only one type of mating surface, although selected others are also contemplated, and will not mate with other female type connectors. Thus a connector designated, for example, for epidural catheter injections is generally incapable of connection to a syringe intended for intravenous injection absent the specially configured surface feature. The identity of the connector type is readily recognizable by the skilled artisan from the shape or design of the mating surfaces, as well as from distinctive markings on the outer

surfaces of the half connectors. These markings can include textured features, color coding and/or text labels, such as labels 70.

Applicants respectfully submit that none of the portions cited by the Examiner, nor the remainder of Segal et al. teach or suggest “a shape of the grip that is suggestive of a part of a human body for which the application is intended” as claimed. Applicants respectfully submit that Segal et al. simply do not anticipate this limitation nor would one skilled in the art be motivated to modify the teachings of Segal et al. to reach “a shape of the grip that is suggestive of a part of a human body for which the application is intended.”

Claim 8 further recites, “wherein said method of interconnection comprises a twisting step; and wherein said mechanism affordance comprises a wing of said grip.” A “wing” protrudes from the remaining structure, as illustrated for example as element 56’ in Figs. 5a and 5b. The Examiner cites to elements 29, 35 and 405 of Segal et al. as constituting wings. Applicants respectfully disagree and submit that Segal et al., do not teach or suggest wings. For example, element 405 of Segal et al. is not for use with a twisting interconnection, but rather snaps into slot 400.

Claim 9 further recites, “wherein said method of interconnection comprises a pushing step; and wherein said mechanism affordance comprises a waist of said grip.” A “waist” is a portion of the grip that is of reduced diameter, as illustrated for example in Fig. 5a. See also paragraph 78 of the published application. Applicants respectfully submit that Segal et al., including col. 7, lines 57 to 67 and Figs. 2 and 6) fail to teach or suggest a grip and a waist as claimed.

Claim 10 further recites, “wherein said method of interconnection comprises a locking step; and wherein said mechanism affordance comprises a button of said grip.” A button is illustrated for example as element 56 in Fig. 8b. The Examiner cites to elements 29 and 35 as constituting a button. These are the same elements the Examiner cited to as constituting a wing with regard to claim 8. Applicants respectfully submit that neither of elements 29 and 35 is a button..

Claim 32, as amended, recites that the male component has a shaft and that the “collar is

axially slidable on the shaft”. Applicants respectfully submit that Segal et al. fail to teach or suggest a grip that is slidable on the shaft of the connector.

Accordingly, Applicants respectfully request that the rejection of claims 1, 2, 7 to 16, 18 to 27, 29, 31 and 32 under 35 U.S.C. §102(b) be withdrawn.

### **Rejections Under 35 U.S.C. §103(a)**

The Examiner rejected claims 3 to 6 and 14 under 35 U.S.C. §103(a) as being unpatentable over Segal et al. (U.S. Patent No. 6,402,207). Applicants respectfully traverse this rejection.

Claims 3 to 6 and 14 depend from claims 1 and 11 respectively and by definition contain all the limitations of claims 1 and 11. As explained, above Segal et al. fail to teach or suggest all of the limitations of claims 1 and 11. Accordingly, Applicants respectfully submit that claims 3 to 6 and 14 are patentable over Segal et al. for the reasons given above for claims 1 and 11 as well as because of the additional limitations contained therein.

Claim 3 further recites “wherein a first application is neuraxial, and said shape of the grip is generally cylindrical having a longitudinal spine and encircling ribs suggestive of the human spine and ribs.” One embodiment of such a grip shape is shown in Fig. 5a. The Examiner cites to the portions reproduced above, col. 8, lines 33 to 49, col. 2, lines 12 to 19, col. 5, lines 31 to 46 and to Figs 5, 7 and 7A for teaching this limitation. Applicants respectfully submit that neither the portions cited by the Examiner, nor the remainder of Segal et al. teach or suggest the above limitation. A review of Fig. 5 reveals a plurality of different cross sectional shapes of the mating ends and Fig. 7A reveals a cylindrical grip having an indented portion. Applicants respectfully submit that the grip shown in Fig. 7A is not suggestive of a human spine and ribs as claimed and that the portions cited by the Examiner do not teach or suggest a grip shape that “is generally cylindrical having a longitudinal spine and encircling ribs suggestive of the human spine and ribs.”

Claim 4 further recites, “wherein a second application is respiratory, and said shape of the grip is generally cylindrical having alternating frusto-conical sections suggestive of a bellows.”

An example of such a grip shape is shown in Figs. 8a and 8b. Applicants respectfully submit that none of Segal et al., including the portions cited by the Examiner, teach or suggest anything similar to the claimed grip shape.

Claim 5 further recites “wherein a third application is enteral, and said shape of the grip is generally cylindrical with bulges down its length suggestive of the human colon.” Examples of such a grip shape are shown in Figs. 9a, 9b and 9c. Applicants respectfully submit that none of Segal et al., including the portions cited by the Examiner, teach or suggest anything similar to the claimed grip shape.

The Examiner states that because Segal discloses making the connectors distinctive in shape and markings for different uses it would have been obvious to a person of ordinary skill in the art at the time the invention was made to make the connectors take on markings and shape of the intended bodily use for reduced errors in the connection. Applicants respectfully disagree and submit that none of the different shapes taught by Segal et al resemble an intended bodily use, and one skilled in the art would have no motivation to do otherwise. Moreover, Applicants respectfully submit that one skilled in the art would have no motivation from any of the cited references to modify the shapes taught by Segal et al. to be suggestive of body parts.

Accordingly, Applicants respectfully submit that claims 3 to 6 and 14 are patentable over Segal et al. and request that the rejection of claims 3 to 6 and 14 under 35 U.S.C. §103(a) be withdrawn.

The Examiner rejected claims 17 and 28 to 30 under 35 U.S.C. §103(a) as being unpatentable over Segal et al. (U.S. Patent No. 6,402,207) in view of Moberg et al. (U.S. Patent No. 6,659,980). Applicants respectfully traverse this rejection.

Claims 17 and 28 to 30 depend from claim 11 and by definition contain all of the limitations of claim 11. As explained above, claim 11 is patentable over Segal et al. Applicants submit that Moberg et al. fail to remedy the defects of Segal et al. Accordingly, claim 11 is patentable over Segal et al. and Moberg et al. considered alone and in combination. Therefore, Applicants respectfully submit that claims 17 and 28 to 30 are patentable over Segal et al. and

Moberg et al. considered alone and in combination for the reasons given above for claim 11 as well as because of the additional limitations contained therein.

Accordingly, Applicants respectfully request that the rejection of claims 17 and 28 to 30 under 35 U.S.C. §103(a) be withdrawn.

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### CONCLUSION

In view of the above amendments and remarks, Applicants believe that all pending claims are in condition for allowance and such action is earnestly requested. If the present remarks do not place the application in condition for allowance, then the Examiner is encouraged to contact the undersigned directly if there are any issues that can be resolved by telephone with the Applicants' representative.

A fee of \$245 is believed due with this communication for a two month extension of time. The Commissioner is hereby authorized to charge payment of this fee and any other fees due with this communication to Deposit Account No. 19-2090.

Respectfully Submitted,

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Date: May 8, 2009

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